

Listing of Claims

This listing of claims will replace all prior listings of claims in the application:

1. (Currently Amended) A non-sustained release, (non-chewable tablet) composition according to claim 39, which comprises a ~~rapidly precipitating drug~~ ^{Super Solen salt of a poorly soluble drug} ~~and only a rapidly precipitating drug~~ as the sole active pharmaceutical ingredient, in an amount from about 5 to 60% ~~and at least one member selected from the group consisting of, a polymeric binder in an amount from about 2 to about 25% and, a~~ superdisintegrant in an amount from about 6 to about 40% and a lubricant in an amount up to about 5%; (a) wherein the rapidly precipitating drug is a fairly soluble or highly soluble salt form of a poorly soluble free base or free acid or an anhydrous form of a poorly soluble free base or free acid that is prone to supersaturation when introduced in water, or simulated physiological fluids at body temperature, begins to dissolve fairly rapidly and then begins to rapidly precipitate out of solution and (b) wherein more than 90% of the rapidly precipitating drug precipitates out within 60 minutes after coming into contact with said water or simulated physiological fluids at body temperature, with the proviso that the rapidly precipitating drug is not delavirdine mesylate. - Stay

2. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the polymeric binder is selected from the group consisting of:

hydroxypropyl methylcellulose,
PVP,
hydroxypropyl cellulose,
methylcellulose,
hydroxyethylcellulose,
carbopol,

sodium carboxymethylcellulose.

3. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 2 wherein the polymeric binder is hydroxypropyl methylcellulose.

4. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 2 wherein the polymeric binder is PVP.

5. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 2 where the polymeric binder is present in the amount as follows for:

hydroxypropyl methyl cellulose of from about 5 to about 20%,
PVP from about 2 to about 15%,
hydroxypropyl cellulose from about 5 to about 20%,
methylcellulose from about 5 to about 20%,
hydroxyethylcellulose from about 5 to about 20%,
carbopol from about 3 to about 20%,
sodium carboxymethylcellulose from about 3 to about 20%.

6. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the superdisintegrant is croscarmellose sodium, sodium starch glycolate, L-hydroxypropyl cellulose.

7. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the superdisintegrant is present in an amount of from about 6 to about 35%.

8. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim

contd

7 where the superdisintegrant is present in an amount of from about 10 to about 30%.

9. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 which contains microcrystalline cellulose in an amount up to about 50%.

10. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to Claim 9 where the microcrystalline cellulose is selected from the group consisting of

microcrystalline cellulose coarse powder
microcrystalline cellulose medium powder and
microcrystalline cellulose 200.

11. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 9 where the microcrystalline cellulose is microcrystalline cellulose N.F. coarse powder.

12. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to Claim 9 where the microcrystalline cellulose is present in an amount of from about 10 to about 40%.

13. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 which contains lactose in an amount up to about 80%.

14. (Previously Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 13 where the lactose is selected from the group consisting of lactose monohydrate spray process standard, lactose monohydrate, lactate anhydrous, lactose dihydrate, DMV lactose.

15. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 13 where the lactose is N.F. monohydrate spray process standard lactose.

16. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 12 where the lactose is present in an amount of from about 5 to about 20%.

17. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 which contains a flow agent in an amount up to 5%.

18. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 17 where the flow agent is selected from the group consisting of colloidal silicon dioxide and talc.

19. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 17 where the flow agent is colloidal silicon dioxide N.F.

20. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the flow agent is present in an amount from 0.25 to about 2%.

21. Cancelled

22. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim ~~21~~ where the lubricant is selected from the group consisting of magnesium stearate and stearic acid.

23. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim ~~21~~22 where the lubricant is magnesium stearate.

24. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the lubricant is present in the amount of 0.25 to about 2%.

25. Cancelled.

26. (Currently Amended) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 1 where the rapidly precipitating drug is present in an amount of from about 10 to about 40%.

27-33. Cancelled.

31 cont'd
34. (Currently Amended) A non-sustained release, non-chewable tablet composition according to Claim ~~13~~3, wherein the polymeric binder is hydroxypropyl methylcellulose of from about 5 to about 20%.

35. (Currently Amended) A non-sustained release, non-chewable tablet composition which comprises a rapidly precipitating drug, and only a rapidly precipitating drug as the sole active pharmaceutical ingredient, in an amount from about 5 to 60% ~~and at least one member selected from the group consisting of,~~ a polymeric binder in an amount from about 2 to about 25% ~~and,~~ a superdisintegrant in an amount from about 6 to 40% and a lubricant in an amount up to about 5%; (a) wherein the rapidly precipitating drug is a fairly soluble or highly soluble salt form of a poorly soluble free base or free acid ~~or an anhydrous form of of a poorly soluble free base or free acid~~ that is prone to supersaturation when introduced in water, or simulated physiological fluids at body temperature,

begins to dissolve fairly rapidly and then begins to rapidly precipitate out of solution and (b) wherein more than 90% of the rapidly precipitating drug precipitates out within 60 minutes after coming into contact with said water or simulated physiological fluids at body temperature, with the proviso that the rapidly precipitating drug is not delavirdine mesylate; and wherein the rapidly precipitating drug, ~~microcrystalline cellulose, polymeric binder and, superdisintegrant~~ superdisintegrant and lubricant are mixed in and compressed into a tablet without heating, solvent or grinding, with the proviso that the rapidly precipitating drug is not delavirdine mesylate.

36. (Currently Amended) A non-sustained release, non-chewable tablet composition according to Claim 35, wherein the mixing is accomplished in a high shear mixer.

37. (Currently Amended) A non-sustained release, non-chewable tablet composition according to Claim 35, wherein the polymeric binder is selected from the group consisting of hydroxypropyl methylcellulose, ~~polyvinylpyrrolidone~~ PVP, hydroxypropyl cellulose, methyl cellulose, hydroxyethylcellulose, carbopol and sodium carboxymethyl cellulose.

Tell them on April or Instant

38. (Currently Amended) A composition according to Claim 1, wherein the rapidly precipitating drug is selected from clindamycin hydrochloride, ~~clonidine~~ clonidine hydrochloride, diphenhydramine hydrochloride, fluphenazine hydrochloride, hydromorphone hydrochloride, naloxone hydrochloride, oxytetracycline hydrochloride, phenylephrine hydrochloride, pheniramine maleate, tetracycline hydrochloride, verapamil hydrochloride, propoxyphene hydrochloride, hydrocodeine bitartrate, acyclovir sodium, albuterol sulfate, ampicillin sodium, benztropine mesylate, benzphetamine hydrochloride, bupivacaine hydrochloride,

bupropin hydrochloride, clorphenamine maleate and chlorpromazine hydrochloride.

39. (New) A non-sustained release, non-chewable tablet composition which comprises a ~~rapidly-precipitating~~ drug, and only a rapidly precipitating drug as the sole active pharmaceutical ingredient, in an amount from about 5 to 60%, a polymeric binder in an amount from about 2 to about 25%, a superdisintegrant in an amount from about 6 to 40% and a lubricant in an amount up to about 5%; (a) ~~wherein the rapidly precipitating drug is~~ a fairly soluble or highly soluble salt form of a poorly soluble free base or free acid or an anhydrous form of a poorly soluble free base or free acid that is prone to supersaturation when introduced in water, or simulated physiological fluids at body temperature, begins to dissolve fairly rapidly and then begins to rapidly precipitate out of solution and (b) wherein more than 90% of the rapidly precipitating drug precipitates out within 60 minutes after coming into contact with said water or physiological fluids at body temperature, with the proviso that the rapidly precipitating drug is not delavirdine mesylate.

1
contd

40. (New) A non-sustained release, non-chewable tablet composition according to claim 39, which comprises a rapidly precipitating drug, and only a rapidly precipitating drug as the sole active pharmaceutical ingredient, in an amount from about 5 to 60%, a polymeric binder in an amount from about 2 to about 25%, a superdisintegrant in an amount from about 6 to 40% and a lubricant in an amount up to about 5%; (a) wherein the rapidly precipitating drug is an anhydrous form of a poorly soluble free base or free acid that is prone to supersaturation when introduced in water, or simulated physiological fluids at body temperature, begins to dissolve fairly rapidly and then begins to rapidly precipitate out of solution and (b) wherein more than 90% of the rapidly precipitating drug precipitates out within 60 minutes after

coming into contact with said water or physiological fluids at body temperature.

41. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the polymeric binder is selected from the group consisting of
hydroxypropyl methyl cellulose,
PVP,
hydroxypropyl cellulose,
methylcellulose,
hydroxyethylcellulose,
carbopol,
sodium carboxymethylcellulose.

42. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 41 wherein the polymeric binder is hydroxypropyl cellulose.

43. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 41 wherein the polymeric binder is PVP.

44. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 41 where the polymeric binder is present in the amount of
hydroxypropyl methyl cellulose of from about 5 to 20% PVP
from about 2 to about 15%
hydroxypropyl cellulose from about 5 to about 20%
methylcellulose from about 5 to about 20%
hydroxy ethylcellulose from about 5 to about 20%
carbopol from about 3 to about 20%
sodium carboxymethylcellulose from about 3 to about 20%.

45. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where

the superdisintegrant is croscarmellose sodium, sodium starch glycolate, L-hydroxypropyl cellulose.

46. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the superdisintegrant is present in amount of from about 6 to about 35%.

47. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 46 where the superdisintegrant is present in amount of from about 10 to about 30%.

48. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 which contains microcrystalline cellulose in amount up to about 50%.

49. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 48 where the microcrystalline cellulose is selected from the group consisting of

microcrystalline cellulose coarse powder
microcrystalline cellulose medium powder and
microcrystalline cellulose 200.

50. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 48 where the microcrystalline cellulose is microcrystalline cellulose N.F. coarse powder.

51. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 48 where the microcrystalline cellulose is present in an amount of from about 10 to about 40%.

52. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 which contains lactose in an amount up to 80%.

53. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 52 where the lactose is selected from the group consisting of lactose monohydrate spray process standard, lactose monohydrate, lactate anhydrous, lactose dihydrate, DMV lactose.

54. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 52 where the lactose is N.F. monohydrate spray process standard lactose.

55. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 51 where the lactose is present in amount of from about 5 to about 20%.

56. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 which contains a flow agent in an amount up to 5%.

57. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 56 where the flow agent is selected from the group consisting of colloidal silicon dioxide and talc.

58. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 56 where the flow agent is colloidal silicon dioxide N.F.

59. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the flow agent is present in an amount from 0.25 to about 2%.

60. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the lubricant is selected from the group consisting of magnesium stearate and stearic acid.

61. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the lubricant is magnesium stearate.

62. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the lubricant is present in the amount of 0.25 to about 2%.

63. (New) A non-sustained release, non-chewable pharmaceutical tablet composition according to claim 40 where the rapidly precipitating drug is present in an amount of from about 10 to about 40%.

64. (New) A tablet composition according to Claim 40, where the rapidly precipitating drug, polymeric binder and superdisintegrant are mixed and compressed into a tablet without heating, solvent or grinding.

65. (New) A tablet composition according to Claim 40, wherein the polymeric binder is hydroxypropyl methyl cellulose of from about 5 to about 20%.

66. (New) A tablet composition according to Claim 64, wherein the mixing is accomplished in a high shear mixer.

67. (New) A tablet composition according to Claim 64, wherein the binder is selected from the group consisting of hydroxypropyl methyl cellulose, ~~polyvinylpyrrolidone~~ PVP, hydroxypropyl cellulose, methylcellulose, hydroxyethylcellulose, carbopol and sodium carboxymethylcellulose.

1
S
concl'd